

REMARKS

This responds to the Office Action dated June 13, 2006.

Claim 8 is amended. Claims 21-25 were added. As a result, claims 1-25 are pending in this application.

Claims 21-25 are new. Applicant respectfully submits that claims 21-25 distinguish over the cited references. Further, Applicant respectfully submits that claims 21-25 are supported by the present specification and, thereby, do not include new matter. Consideration and allowance of claims 21-25 are respectfully requested.

§112 Rejection of the Claims

Claims 8 (and 9-14 depending therefrom) were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 8 was amended to clarify the subject matter therein. The amendment makes express what was implicit in the claims as originally worded. Reconsideration and withdrawal of the rejection of claim 8 and claims 9-14 dependent therefrom are respectfully requested.

§102 Rejection of the Claims

Claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 were rejected under 35 USC § 102(b) as being anticipated by Huepenbecker et al. (U.S. Patent No. 6,289,251). Applicant respectfully traverses this rejection.

In order for a prior art reference to anticipate under 35 U.S.C. § 102, “every element of the claimed invention must be identically shown in a single reference.” (emphasis added). *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In addition, in order to anticipate the elements in the single reference “must be arranged as in the claim under review.” *Id.*, (quoting *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984)). Finally, “the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo N.V. v. United States Int’l Trade*

Comm'n, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1989).

Applicant cannot find all of the elements of the claims in Huepenbecker. For instance, Applicant cannot find in Huepenbecker a recessed portion recessed away from the bottom surface of the tine when the tine is disposed in the second collapsed position, as recited in claims 1 and 14, or forming a first recessed portion along the lead body along the tine interface portion including recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position, as recited in claim 15. Applicant further cannot find in the reference the first portion along the tine interface second having a first cross-sectional shape that is different than a second cross-sectional shape, as recited in claim 8. Claims 3, 4, 6, and 7 also include the recitations of claim 1, claims 9, 10, and 14 include the recitations of claim 8, and claims 16, 19, and 20 include the limitations of claim 15. For at least this reason, claims 3, 4, 6, 7, 9, 10, 14, 16, 19, and 20 are likewise not anticipated by Huepenbecker.

Applicant notes that Huepenbecker does not include any figures illustrating tines in a collapsed position. According to the Office Action at page 3, “when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.” In the Response to Arguments section at page 12, the Office Action further states that “the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.” Applicant can find no disclosure in Huepenbecker of the tines collapsing and, more importantly, Applicant can find no disclosure of the tines being recessed away from a first recessed portion. Applicant respectfully submits that Huepenbecker does not enable such statements, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

With respect to claims 3, 9, 19, and 20, the Office Action states at page 4, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” While it is unclear on what the Office Action relies to make such a statement, Applicant cannot find support in the specification for such an assertion. Applicant wonders how the Office Action can draw such a conclusion having only one cross section of the lead taken along an axial plane in Fig. 4 of Huepenbecker. Applicant asserts that one skilled in the art could not determine the cross-sectional areas of what the Office Action identifies as the first and second recessed portions of Huepenbecker given only a cross section along a single axial plane. Applicant submits that Huepenbecker does not anticipate claims 3, 9, 19, and 20, and is not an enabling reference. Reconsideration and allowance of claims 3, 9, 19, and 20 are respectfully requested.

Applicant notes that Huepenbecker does not state the drawings are to scale. “It is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.” *Hockerson-Halberstadt v. Avia Group International, Inc.*, 222 F.3d 951, 956 (citing *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977)). The Office Action states on page 4, “it appears from Figure 4 that the cross-sectional area at the lead distal end . . . is approximately the same as the cross-sectional area of the tine coupling portion. Accordingly, the cross-sectional area of the tine coupling area is necessarily ‘less than 10% smaller’ than the cross-sectional area of the lead distal end.” The Office Action states on page 13 that “the claims as written do not require any precise proportions or sizes of the first and second recessed portions.” However, because the drawings of Huepenbecker do not define precise proportions and the specification is completely silent with respect to the issue, Applicant respectfully asserts that the drawings of Huepenbecker cannot be used to anticipate claim 4, which recites “the first cross-sectional area is less than 10% smaller than the second cross-sectional area”. Accordingly, Applicant asserts that the rejection is improper, and reconsideration and allowance of claim 4 are respectfully requested.

With respect to claim 7, the Office Action states at pages 4-5 that “[a]s shown in Fig. 4, the diameters of the spacer 34, the first recessed portion, and the second recessed portion are each different from one another.” With respect to claim 8, the Office Action states at page 5, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of

the second recessed portion.” In the Response to Arguments section at page 13, the Office Action essentially reiterates this statement, further stating that “Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape.” Applicant cannot find support in the specification for these assertions. Applicant can find no disclosure related to the cross-sectional areas of any portions of the Huepenbecker device. Further, it is unclear how these conclusions can be reached when Figure 4 only illustrates a longitudinal cross-section. Accordingly, reconsideration and allowance of claims 7 and 8 are respectfully requested.

For at least these reasons, Applicant respectfully asserts that claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 are not anticipated by Huepenbecker and requests reconsideration and withdrawal of this rejection.

Claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 were rejected under 35 USC § 102(b) as being anticipated by Laske et al. (U.S. Patent No. 5,807,399). Applicant respectfully traverses this rejection.

Applicant cannot find all of the elements of the claims in Laske. For instance, Applicant cannot find in Laske a recessed portion recessed away from the bottom surface of the tine when the tine is disposed in the second collapsed position, as recited in claim 1 and 14, or forming a first recessed portion along the lead body along the tine interface portion including recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position, as recited in claim 15. Applicant further cannot find in the reference the first portion along the tine interface second having a first cross-sectional shape that is different than a second cross-sectional shape as recited in claim 8. Claims 3, 4, 6, and 7 also include the limitations of claim 1, claims 9, 10, and 14 include the limitations of claim 8, and claims 16, 19, and 20 include the limitations of claim 15 and are likewise not anticipated by Laske. For at least this reason, claims 3, 4, 6, 7, 9, 10, 14, 16, 19, and 20 are likewise not anticipated by Laske.

Applicant notes that Laske does not include any figures illustrating tines in a collapsed position. According to the Office Action at page 6, “when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.” In the Response to Arguments section at pages 14-15, the Office Action further states that

“the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.” Applicant can find no disclosure in Laske of the tines collapsing and, more importantly, Applicant can find no disclosure of the tines being recessed away from a first recessed portion. Applicant respectfully submits that Laske does not enable such statements, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

With respect to claims 3, 9, 19, and 20, the Office Action states at page 6, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” While it is unclear on what the Office Action relies to make such a statement, Applicant cannot find support in the specification for such an assertion. Applicant wonders how the Office Action can draw such a conclusion having only one cross section of the lead taken along an axial plane in the figures of Laske, and, in particular, Fig. 5 referenced by the Office Action. Applicant asserts that one skilled in the art could not determine the cross-sectional areas of what the Office Action identifies as the first and second recessed portions of Laske given only a cross section along a single axial plane. Applicant submits that Laske does not anticipate claims 3, 9, 19, and 20, and is not an enabling reference. Reconsideration and allowance of claims 3, 9, 19, and 20 are respectfully requested.

Applicant notes that Laske does not state the drawings are to scale. With respect to claim 4, the Office Action states on page 6, “it appears from Figure 5 that the cross-sectional area at the lead distal end is slightly larger than the cross-sectional area of the tine coupling portion. Examiner considers the cross-sectional area of the tine coupling area to be approximately ‘less than 10% smaller’ than the cross-sectional area of the lead distal end.” Initially, Applicant asserts that the Examiner is using personal knowledge, and Applicant requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Additionally, as stated above, the specification fails to state the drawings are to scale. The Office Action states on page 15 that “the claims as written do not require any precise proportions or sizes of the first and second recessed portions.”

However, because the drawings of Laske do not define precise proportions and the specification is completely silent with respect to the issue, Applicant respectfully asserts that the drawings of Laske cannot be used to anticipate claim 4, which recites “the first cross-sectional area is less than 10% smaller than the second cross-sectional area”. Accordingly, Applicant asserts that the rejection is improper, and reconsideration and allowance of claim 4 are respectfully requested.

With respect to claim 7, the Office Action states at page 7 “the length of the first recessed portion is less than the tine length,” and “[a]s shown in Fig. 5, the diameters of the sheath 122, the first recessed portion, and the second recessed portion are each different from one another.” With respect to claim 8, the Office Action states at page 7, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” In the Response to Arguments section at page 15, the Office Action essentially reiterates this statement, further stating that “Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape.” Applicant cannot find support in the specification for these assertions. Applicant can find no disclosure related to the cross-sectional areas of any portions of the Laske device. Further, it is unclear how these conclusions can be reached when the figures of Laske, in particular Fig. 5 as referenced by the Office Action, only illustrates a longitudinal cross-section. Accordingly, reconsideration and allowance of claims 7 and 8 are respectfully requested.

For at least these reasons, Applicant respectfully asserts that claims 1, 3, 4, 6-10, 12, 14-16, 19, and 20 are not anticipated by Laske and requests reconsideration and withdrawal of this rejection.

§103 Rejection of the Claims

Claims 2, 5, 11, 13, 17, and 18 were rejected under 35 USC § 103(a) as being unpatentable over Huepenbecker et al. in view of Alferness et al. (U.S. Patent No. 5,531,781). Applicant respectfully traverses the rejection.

To establish a *prima facie* case of obviousness, a prior art reference must teach all of the claim limitations. MPEP § 2143, *In re Royka*, 490 F.2d 981 (CCPA 1974). Applicant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Applicant incorporates the above-discussion with

respect to the independent claims, and how Huepenbecker fails to establish all of the elements. Alferness does not supply the missing elements.

Notwithstanding that all of the elements cannot be found in the cited references, the Office Action fails to provide a legally sufficient motivation to combine the references. The Office Action states at page 8 “[i]t would have been obvious . . . in order to ensure that lead body is sufficiently strong during implantation.” The Office Action further states on page 16 that “the motivation to combine the references . . . is based on common sense and in the knowledge generally available to one of ordinary skill in the art. Added material in the area of recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient’s vasculature system to the implantation site of the endocardium.” Applicant respectfully submits that these statements are unsupported by the cited references. Applicant respectfully submits that neither Huepenbecker nor Alferness enables such statements, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertions. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertions, or in the alternative, withdrawal of these assertions from the rejection. Furthermore, it is unclear why Huepenbecker would be in need of such a selective modification. Reconsideration and allowance of claims 2, 5, 11, and 17 are respectfully requested.

Claims 2, 5, 11, and 17 were rejected under 35 USC § 103(a) as being unpatentable over Laske et al. Claims 13 and 18 were rejected under 35 USC § 103(a) as being unpatentable over Laske et al. in view of Alferness et al. Applicant respectfully traverses the rejections.

Applicant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Applicant incorporates the above-discussion with respect to the independent claims, and how Laske fails to establish all of the elements. Applicant submits that Alferness does not supply the missing elements.

Notwithstanding that all of the elements cannot be found in Laske (or Alferness), the Office Action fails to provide a legally sufficient motivation to combine the references. The Office Action states at pages 9-10 “[i]t would have been obvious . . . to modify the external

groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body (so long as the sheath 122 may be readily separated when force is applied thereto) in order to ensure that sheath 122 is sufficiently strong during implantation.” The Office Action further states on page 16 that “the motivation to combine the references . . . is based on common sense and in the knowledge generally available to one of ordinary skill in the art. Added material in the area of recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient’s vasculature system to the implantation site of the endocardium.” Applicant respectfully submits that these statements are unsupported by the cited references. Applicant respectfully submits that Laske (or Alferness) does not enable such statements, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertions. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertions, or in the alternative, withdrawal of these assertions from the rejection.

Furthermore, when considered as a whole, Laske teaches away from making the selective modification as suggested in the Office Action. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). The purpose of element 152 of Laske is to create a weakened portion. (*See* Laske et al., col. 7, lines 15-31.) To use hindsight reconstruction and say element 152 could be made to extend only partially around the perimeter to strengthen the lead is opposite of what the reference describes, and would frustrate the purpose of element 152, that is, to allow the lead to separate. Element 152 of Laske is designed to allow

for a weakened portion of the lead, which teaches away from trying to use the same element to make the lead stronger. Accordingly, reconsideration and allowance of the claims are respectfully requested.

Documents Cited But Not Relied Upon For This Office Action

Applicant need not reach the assertions of similarity stated in paragraph 15 on pages 17 of the Office Action, because these patents are not made part of the rejections in this Office Action. Applicant is expressly not admitting to these assertions.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3275 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

JAIME L. RUGNETTA ET AL.

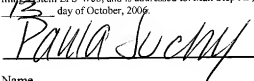
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Date October 13, 2006

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13 CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 13 day of October, 2006.


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